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| 10/557,283 | 11/30/2006 | Subroto Chatterjee | 61383(71699) | 9024 |

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| EXAMINER |
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HOWARD, ZACHARY C

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|-----------------------------------------------------------------------|--------------------------------------|------------------------------------------|
| Advisory Action Before the Filing of an Appeal Brief | Application No. 10/557,283 | Applicant(s) CHATTERJEE ET AL. |
| | Examiner ZACHARY HOWARD | Art Unit 1646 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 April 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 12 April 2011. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☒ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-6, 8 and 39.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

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| | /Bridget E Bunner/ Primary Examiner, Art Unit 1647 |
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Continuation of 3. NOTE:

3(a). The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because they raise new issues that would require further consideration and/or search.

Specifically, proposed claim 2 is directed to a method of claim 39 wherein the enriched HDL is large HDL. In view of parent claim 39, proposed claim 2 is directed to a method of determining whether a subject is at risk for developing atherosclerosis-associated plaque rupture or myocardial infarction comprising (a) measuring the level of ApoC1-enriched large HDL in a biological sample from the subject and (b) comparing the level of ApoC1-enriched large HDL in the biological sample from the subject to the level of ApoC1-enriched large HDL from a control, wherein an increased level of ApoC1-enriched HDL in the biological sample as compared to the control indicates that the subject is at increased risk for developing atherosclerosis-associated plaque rupture or myocardial infarction.

Thus, proposed claim 2 is directed to a method wherein the assessment (prognosis) is made based on the quantity of "large HDL" associated with ApoC1 rather than the quantity of "HDL" associated with ApoC1. Large HDL is the subset of total HDL having large-sized particles.

This is a new embodiment that was not previously recited in the claims, and would require further search and consideration of whether the specification enables and describes such a method under 35 U.S.C. 112, 1st paragraph. The specification uses the term large HDL only in the Examples, and appears to only use the quantity of large HDL to distinguish two population groups, and does not measure the amount of ApoC1 associated with the large HDL fraction (as opposed to total HDL), or associate an increase in such with increased risk.

Furthermore, the dependency of proposed claims 4-6 and 8 has been changed from claim 1 (proposed cancellation) to claim 39. These changes would require further search and consideration of whether the specification provides enablement and description of each of the narrower embodiments of the dependent claims under 35 U.S.C. 112, 1st paragraph. These embodiments were previously only considered as they applied to claim 1, which differed in scope from claim 39.

3(b). The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because they raise the issue of new matter.

Proposed claim 2 is described above. Large HDL is the subset of total HDL having large-sized particles, and thus proposed claim 2 is directed to a narrower embodiment of the parent method. The specification as originally filed does not appear to contain support for the claim as amended, and thus entry of the amendments would require consideration of a new matter rejection under 35 U.S.C. 112, 1st paragraph. The specification uses the term large HDL only in the Examples, and appears to only use the quantity of large HDL to distinguish two population groups, and does not measure the amount of ApoC1 associated with the large HDL fraction (as opposed to total HDL), or associate an increase in such with increased risk.